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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/984,099 12/03/97 MCBRIDE

K CGNE-115-1-U

EXAMINER

HM12/0907

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ART UNIT

PAPER NUMBER

1638

DATE MAILED:

09/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/984,099

Applicant(s)

MCBRIDE ET AL.

Examiner

Amy Nelson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-16, 18-26, 28, 30-39, 42, 44-55, 57, 59, 61 and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-16, 18-26, 28, 30-39, 42, 44-55, 57, 59, 61 and 65-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The rejections under 102(b), 102 (e), and 103(a) have been withdrawn in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

2. Claims 1-10, 12-16, 18-23, 28, 30-39, 42, 44-55, 57, and 59 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 2/6/01. Applicant's arguments filed 7/9/01 have been fully considered but they are not persuasive.

Applicant asserts that Applicant has described several fiber specific promoters. Applicant cites pages 31 and 32 of the specification to support preferred expression in the cotton fiber, and Applicant cites Examples 5 and 6 as support for the 4-4 promoter region and the rac13 promoter region, respectively. The 4-4 promoter region is nucleotides 65-4163 of SEQ ID NO:7 and nucleotides 57-4155 of SEQ ID NO:11. The rac13 promoter region is SEQ ID NO:15 (response, p. 10-11). Examiner responds that pages 31 and 32 are directed to expression of coding sequences and provide no definitive evidence for promoter regions that allow expression of an operably linked coding sequence. Examples 5 and 6 only provide guidance for preparation of

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DNA constructs. As discussed in the previous office action, Applicant only describes a region of the 4-4 upstream region that has promoter activity, namely the region present in pCGN5148, pCGN5149, and pCGN5616. Applicant is asked to point to support in the specification indicating that the region present in those vectors is nucleotides 65-4163 of SEQ ID NO:7. Furthermore, Applicant has not demonstrated that SEQ ID NO:15 has promoter activity, *i.e.* provides for expression of an operably linked coding DNA in cotton fiber cells. Hence, SEQ ID NO:15 is not definitively a promoter, and hence Applicant has not described a transcription initiation region comprising SEQ ID NO:15.

3. Claims 1-10, 12-16, 18-26, 28, 30-39, 42, 44-55, 57, 59, 61, 65 and 66 remain rejected and new Claims 67 and 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to the 4-4 promoter of pCGN5148, pCGN5149, and pCGN5616, as well as vectors, plant cells, and plants comprising said promoter operably linked to a coding sequence, and a method of modifying fiber color by transformation with said promoter operably linked to a DNA encoding tyrosinase, tryptophanase or indole oxygenase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 2/6/01. Applicant's arguments filed 7/9/01 have been fully considered but they are not persuasive.

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Applicant argues that Applicant has described several promoter sequences that direct expression in fiber, and Applicant exemplifies one of the promoters to express several genes in fiber cells. Hence, Applicant submits that it would be possible to combine the promoters with other genes for expression in fiber cells (response, p. 11). Examiner responds that as discussed in the last Official action, Applicant has only provided guidance for the upstream region from the 4-4 coding sequence present in pCGN5148, pCGN5149, and pCGN5616, and shown it to have promoter activity. Applicant is requested to point to support in the specification to indicate that the promoter region present in those constructs is the sequence of nucleotides 65-4163 of SEQ ID NO:7. Applicant has provided no guidance to indicate that SEQ ID NO:15 has promoter activity. In the absence of clear guidance that each of the claimed sequences functions as a promoter, the instant claims to promoters are not enabled. Because Applicant has not taught another use for the claimed nucleic acid sequences, Claims 23, 24, 61, 65 and 66 are likewise not enabled. Furthermore, although it would be routine to operably link any coding DNA to a promoter sequence, instant Claim 14, for example, is directed to a method of modifying fiber phenotype. Manipulation of phenotype in plants is highly unpredictable. Applicant has only provided guidance for a method of modifying fiber color by transformation with a DNA encoding tyrosinase, tryptophanase or indole oxygenase. Applicant provides no guidance for other DNA coding sequences, including DNA coding sequences encoding SEQ ID NO:2 and SEQ ID NO:13. In fact, Applicant provides no guidance for how to use DNA coding sequences encoding SEQ ID

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NO:2 and SEQ ID NO:13. Hence, the invention is not enabled throughout the broad scope of the claims.

4. Claims 4, 5, 10, 14-16, 18-22, 31-33, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 4, the phrase "a transit peptide from a signal peptide which provides for transport across the rough endoplasmic reticulum" is unclear. The claim should recite either a transit peptide or a signal peptide. It is recommended that the phrase be changed to --a signal peptide which provides for transport across the rough endoplasmic reticulum--.

At Claim 10, lines 2-3, "the open reading frame ... encodes a different gene" does not make sense. A DNA does not encode a gene, but rather a protein. Appropriate correction is required.

At Claim 14, line 1, the phrase "modifying fiber phenotype" is indefinite because it is not clear what is encompassed by the phrase. Fiber tissue has many different phenotypes which can be modified in many different ways. Appropriate correction is required to clarify the metes and bounds of the claimed invention. The phrase "phenotype of said fiber" at line 7 should be changed accordingly. Applicant asserts that Applicant has provided a definition and examples for the phrase (response p. 12). Examiner requests that Applicant point to a definition for the phrase in

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the instant specification. In the absence of a clear definition, it is submitted that the metes and bounds of the phrase are unclear.

At Claim 16, the phrase "a transit peptide, which encodes a signal peptide which provides for transport across the rough endoplasmic reticulum" is unclear. A peptide does not encode another peptide, rather a DNA encodes a peptide. Also, the claim should recite either a transit peptide or a signal peptide. It is recommended that the phrase be changed to --a signal peptide which provides for transport across the rough endoplasmic reticulum--.

Claim 18 is improperly dependent on Claim 16. Applicant appears to intend to modify the method by adding an additional method step. Hence, the claim should recite --The method of Claim 16 further comprising transforming...--. Also, "the open reading frame ... encodes a different gene" does not make sense. A DNA does not encode a gene, but rather a protein. Appropriate correction is required.

At Claim 31, "said transport signal encoding sequence comprises a plastid transit peptide" does not make sense. It is not clear how a DNA can comprise a peptide.

At Claim 32, the phrase "a transit peptide which provides for transport across the rough endoplasmic reticulum" is unclear because a signal peptide, not a transit peptide is involved in transport to the ER. It is recommended that the phrase be changed to --a transit peptide which provides for transport across the rough endoplasmic reticulum--.

At Claim 47, the phrase "a transit peptide which provides for transport across the rough endoplasmic reticulum" is unclear because a signal peptide, not a transit peptide is involved in

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transport to the ER. It is recommended that the phrase be changed to --a transit peptide which provides for transport across the rough endoplasmic reticulum--.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:30 AM - 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Yolanda Vines, whose telephone number is (703) 305-2365.



AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.

September 6, 2001